

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Robert S. Biscup
For : EXPANDABLE SPHERICAL SPINAL IMPLANT
Serial No. : 10/801,975
Filed : March 16, 2004
Examiner : Anuradha Ramana
Group Art Unit : 3775
Our Docket : MEDR 2 00001

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The Applicants request Pre-Appeal Brief Review of the final rejections in the above-identified patent application. No amendments are being filed with the request. This request is being filed with a Notice of Appeal. The Applicant respectfully submits the following five (5) pages which identify reasons for requesting Pre-Appeal Brief Review.

Respectfully submitted,

FAY SHARPE LLP

4/6/09
Date

By: 

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The Present Application - The present application is directed to a prosthetic implant that is to be inserted between the vertebrae of the spine and a method for using the prosthetic implant.

The prosthetic implant defined in the independent claims to require that a portion of the body include an expandable component. Independent claim 1 requires the expandable component to at least partially form a stabilizer, wherein **the stabilizer in an expanded state has a perimeter that is greater than a perimeter of the body**. Independent claim 55 requires the expandable region on the body of the implant **to have a perimeter that is greater than a perimeter of said non-expandable region when the expandable region is in an expanded state**. Independent claim 80 requires that at least one material of the at least one expandable component **to chemically react** and form an expanded composition until the at least one expandable component at least partially expands while said non-expandable component substantially retains its same form. These limitations are not disclosed, taught or suggested by Kuslich (US 5,571,189).

Additionally, it is noted that several of the dependent claims (e.g., 2, 6-8, 14-23, 25, 26, 30, 32 and 36) include structural limitations that further distinguish the expandable component of the claimed implant from the implant disclosed in Kuslich.

The Cited Reference - The only reference cited against the pending claims is Kuslich. Kuslich discloses a flexible fabric implant. (Col. 3, lns. 61-62). The flexible fabric includes an opening that may receive biological fill material to cause the flexible fabric to expand and conform to the cavity formed in the disc. (Col. 3, lns. 62-67). The flexible fabric is porous. (Col. 4, lns. 4-8). The flexible fabric implant includes an equatorial band that controls the shape of the expanded flexible fabric. (Col. 4, lns. 9-15). Figures 1, 2, 8, 9, 50, and 51 best illustrate the flexible fabric implant.

Kuslich specifically describes the flexible fabric implant 40 as a small fabric bag that is roughly spherical in shape when the bag is expanded; however, the expanded bag can be elliptical or have other shapes. (Col. 6, lns. 57-60). The flexible fabric implant 40 also includes an equatorial band 42 that confines the expanded bag at about the center or equator of the bag. (Col. 6, lns. 60-66). The bag fabric is described as pliable, malleable and porous material. (Col. 6, ln. 67; Col. 7, lns. 1-52). Most of the Figures of Kuslich disclose and describe the flexible fabric implant 40 as being formed from a single flexible bag. Figures 50 and 51 of Kuslich disclose a bag 10 that is formed of two hemispheres 160, 162 and a central band 164. (Col. 11, lns. 16-37). The three layers of 160, 162, 164 form a stiffer region. It is respectfully submitted that Kuslich does not disclose the prosthetic implant defined in the

claims. Figure 14 illustrates that band 42 can also be formed of multiple layers of fabric. (Col. 10, lns. 7-9).

The 112 Rejection - The examiner asserted that claim 2 was not supported by the originally filed application since claim 2 implies that the body could be expandable, thus such teaching is not supported by the originally filed Specification. Claim 1 defines the body as including the at least one expandable component. As such, at least a portion of the body must be expandable. Claim 2 further limits claim 1 to require a majority of the body is non-expandable. This is illustrated in Figures 1, 2 and 13-18.

The Section 102 Rejection - The examiner asserted on Page 3 of the Final Office Action that Kuslich discloses a spherical bag 40. The examiner appears to assert that the material inserted into the bag could be considered an unexpandable component. Even if this interpretation of Kuslich is followed, Kuslich still does not disclose an expanded stabilizer that in an expanded state has a perimeter that is greater than the perimeter of the body. Using the examiner's interpretation, the bag, when filled with the unexpandable component becomes the spherical or ellipsoidal body as illustrated in Figures 1, 2, 6, 7, 7a, 8, 9, 10, 22, 26, 50 and 51 of Kuslich. Once the bag is filled and forms the spherical or ellipsoidal body, the only component left is the unexpandable band 42. Since band 42 is not expandable, it cannot be the expandable stabilizer as defined in the pending claims. As such, the examiner's first interpretation of Kuslich does not disclose, teach or suggest the prosthetic implant defined in the pending claims.

The examiner set forth an alternative interpretation of Kuslich on Page 3 of the Final Office Action when asserting Kuslich against claims 78 and 80. The examiner asserted that band 42 is the non-expanded component and the fabric bag is the expandable component. Claim 78 requires there exist a spherical or ellipsoidal body that includes a non-expandable component and an expandable component. As mentioned above, the bag that forms the implant of Kuslich does not have a spherical or ellipsoidal shape until the bag is expanded. Claim 78 also requires that a portion of the spherical or ellipsoidal body be expanded while the non-expandable component retains its shape. In order for the examiner to assert that all of the limitations of claim 78 are disclosed by Kuslich, the examiner has to assert that the bag of Kuslich is both an unexpandable and expandable structure. As is evident from the teachings of Kuslich, the bag does not have an unexpandable component. The same flaws in the examiner's analysis apply to claim 80. The examiner also asserted that hydroxyapatite expands when it hardens. Hydroxyapatite is a second-generation calcium supplement derived from bovine bone.

There is no teaching in Kuslich that such compound has any type of expansion properties when the compound hardens. Applicant also questions whether the examiner's assertion is correct since such compound exists in solid form.

Applicant notes that on Page 4 of the Final Office Action the examiner asserted that Kuslich discloses multiple layers of fabric forming band 42. A similar teaching is also found in Figures 50 and 51 and described in Column 11 lines. 16-37). Applicant notes that Kuslich teaches that the multiple fabric layers stiffen or rigidify the multi-layer region. Such disclosure in Kuslich does not teach an expandable region. Applicant respectfully submits that one of the fundamental differences between Kuslich and the implant defined in the claims is the components that are expandable and non-expandable. As is defined in the claims, the body implant is partially, mostly or completely unexpandable, and the stabilizer is formed of an expandable material that allows the stabilizer to extend beyond the outer perimeter of the body. This type of implant is fundamentally different from the implant disclosed in Kuslich.

For the above reasons, the Final Office Action includes clear errors with regard to the pending independent claims.

In addition to the fact that Kuslich does not anticipate or make obvious any of the pending independent claims, Kuslich does not anticipate dependent claims 2, 6-8, 14-22, 25, 30, 32 and 36. The novel limitations of these dependent claims are highlighted as follows:

- Claim 2: Majority of the substantially spherical or ellipsoidal body is non-expandable; the listing of materials of the non-expandable spherical or ellipsoidal body.
- Claims 6-7: The at least one expandable component is expandable at least partially about an outer surface of the substantially spherical or ellipsoidal body.
- Claim 8: The at least one expandable component at least partially expands into a substantial disc shape.
- Claim 14: The at least one expandable component has a maximum radial expanded width that is up to 300% the maximum diameter of the substantially spherical or ellipsoidal body.
- Claim 15: The expanded radial width of the at least one expandable component is substantially constant.
- Claim 16: The expanded radial width of the at least one expandable component is variable.
- Claim 17: The at least one expandable component has a maximum expanded thickness that is

less than a maximum diameter of the substantially spherical or ellipsoidal body.

- Claim 18: The expanded thickness of the at least one expandable component is substantially constant.
- Claim 19: The expanded thickness of said at least one expandable component is variable.
- Claim 20: The at least one expandable component is expandable radially outwardly from the substantially spherical or ellipsoidal body along a substantially constant axis.
- Claim 21: The at least one expandable component is expandable radially outwardly from the substantially spherical or ellipsoidal body at an angle that deviates from a substantially constant axis.
- Claim 22: The at least one expandable component has an expanded thickness adjacent to the substantially spherical or ellipsoidal body that is different from an expanded thickness of the at least one expandable component at a location spaced from the substantially spherical or ellipsoidal body.
- Claim 25: The substantially spherical or ellipsoidal body includes two hemispherical or two semi-hemispherical portions, the at least one expandable component is positioned between the two hemispherical or two semi-hemispherical portions.
- Claim 30: The expandable pouch is at least partially hardenable.
- Claim 32: The elastic material includes an expandable wall at least partially positioned between the two hemispherical or two semi-hemispherical portions of the substantially spherical or ellipsoidal body.
- Claim 36: Less than a majority of the volume of the substantially spherical or ellipsoidal body includes the at least one cavity.

None of the highlighted limitations of the above dependent claims are disclosed, taught or suggested by Kuslich. Indeed, none of these dependent claims are specifically addressed by the examiner in the Final Office Action.

For the above reasons, the Final Office Action includes clear errors with regard to the above identified pending dependent claims.

The Section 103 Rejection - The examiner asserted on Page 4 of the Final Office Action that the

limitations in dependent claims 14 and 23 were not expressly disclosed in Kuslich; however, such claims were obvious in view of Kuslich.

Dependent claim 14 includes the limitation that the at least one expandable component has a maximum radial expanded width that is up to 300% the maximum diameter of the substantially spherical or ellipsoidal body. The examiner stated that the tapered edge limitation is a mere dimensional limitation, thus obvious in view of the band disclosed in Kuslich. Band 42 is not an expandable component of the implant of Kuslich as established above. As such, an expansion requirement regarding band 42 is irrelevant. The examiner asserted that the expansion limitation would not cause claimed implant to perform differently from the implant disclosed in Kuslich. As discussed above, the implant defined in the claim is structurally different from the implant disclosed in Kuslich, and the claimed implant includes the use of a stabilizer that causes the claimed implant to function differently from the implant disclosed in Kuslich when inserted between two vertebrae. As such, the expansion limitation may be meaningless to the implant disclosed in Kuslich since the band does not expand, but the expansion limitation is not an irrelevant limitation since too great of expansion of the stabilizer can interfere with the proper operation of the implant as can be ascertained from Figure 2. For the above reasons, the Final Office Action includes clear errors with regard to the above identified pending dependent claim 14.

Dependent claim 23 includes the limitation that the at least one expandable component includes at least one tapered edge in an expanded state. As discussed above, the expandable bag of Kuslich is not the same as or equivalent to the expandable stabilizer defined in the claims. Band 42 disclosed in Kuslich is not expandable, and does not function as a stabilizer. Furthermore, band 42 does not have a tapered edge. The examiner stated that the taper feature is not disclosed as having any advantage, thus is obvious in view of the band disclosed in Kuslich. One skilled in the art upon viewing Figure 2 would understand that tapering of the stabilizer allows for additional movement of the implant when positioned between the vertebrae. For the above reasons, the Final Office Action includes clear errors with regard to pending dependent claim 23.

Applicant submits that for at least the reasons set forth above, none of the pending claims are anticipated or made obvious by the teachings of Kuslich. Accordingly, the attention of the Reviewers is directed to the Final Office Action mailed February 3, 2009 and the Pre-Appeal Review, and reversal of the examiner's decisions is respectfully requested.